REMARKS

Claim Status

Claims 20-38 are pending in the application, wherein claims 33-34 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 20, 23, 24, 28, 29-31, and 37-38 have been amended. Claims 21, 22, 25-27, and 35-36 have been canceled without prejudice to Applicant's right to pursue the subject matters in a future application.

Claims Objections

Claims 20, 23, 24, 26, and 31 are objected for various informalities. Applicant submits that appropriate corrections have been made.

Rejection Under 35 U.S.C. §102(b)

1. Claims 20-28, 31-32, and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Pather et al. (U.S. Patent No. 6,280,770) as evidenced by Yang et al. (J. Pharmaceutical Sciences 68:560 (1979)). The rejection is respectfully traversed.

The Examiner contends that Pather discloses microemulsion as solid dosage forms for oral administration comprising drug-containing microemulsions absorbed onto solid particles. The Examiner cites Yang et al. to show that the silica used by Pather is inherently porous and has a surface area greater than 100 m^2/g.

Claim 20 is drawn to a composition comprising water-insoluble or poorly soluble compounds that dissolve in melted lipids, wherein the lipids are GELUCIRE or vitamin E TPGS. Preparation of a microemulsion for an insoluble ingredient is a difficult process, and many compounds cannot form an emulsion or microemulsion (for which water is the continuous phase). But they can easily dissolve in a melt of lipids mixture of amphiphilic nature. A drug-lipid mixed (solidified drug-lipid melt), however, does not necessarily form an emulsion or microemulsion (considered an apparent solution) upon hydration during a dissolution process. Selecting a lipids mixture is critical to achieve a rapid dissolution of an insoluble or poorly soluble drugs from a solidified drug-lipid melt. The present invention demonstrates that the uses of lipids such as GELUCIA and vitamin E TPGS would result in rapid dissolution of an insoluble or poorly soluble drugs from a solidified drug-lipid melt (*see e.g.* page 10, lines 1-10).

Neither Pather et al. nor Yang et al. teach or suggest using GELUCIRE or vitamin E TPGS to make a composition with enhanced dissolution rate. Hence, Pather et al. as evidenced by Yang et al. do not teach or suggest each and every aspect of claim 20. Claims 21, 22, 25-27, 35, and 36 have been canceled without prejudice. Accordingly, Applicant respectfully requests that the rejection of claims 20, 23-24, 28, 31-32, and 37-38 under 35 U.S.C. 102(b) be withdrawn.

2. Claims 20, 22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheth et al. (Drug Development and Industrial Pharmacy, 16:769 (1990)) as evidenced by Yang et al.

(J. Pharmaceutical Sciences 68:560 (1979)). The rejection is respectfully traversed.

The Examiner contends that Sheth discloses free-flowing powder compositions compressed into tablet formulations by direct compression. However, neither Sheth nor Yang teach or suggest using GELUCIRE or vitamin E TPGS to make a composition with enhanced dissolution rate as claimed herein. Hence, Sheth et al. as evidenced by Yang et al. do not teach or suggest each and every aspect of claim 20. Claims 22 and 27 have been canceled without prejudice. Accordingly, Applicant respectfully requests that the rejection of claim 20 under 35 U.S.C. 102(b) be withdrawn.

3. Claims 20, 22, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (J. Pharmaceutical Sciences 68:560 (1979)). The rejection is respectfully traversed.

The Examiner contends that Yang discloses the effects of amorphous silicon dioxides on drug dissolution. As discussed above, however, Yang et al. do not teach or suggest using GELUCIRE or vitamin E TPGS to make a composition with enhanced dissolution rate as claimed herein. Hence, Yang et al. do not teach or suggest each and every aspect of claim 20. Claims 22 and 27 have been canceled without prejudice. Accordingly, Applicant respectfully requests that the rejection of claims 20 and 28-30 under 35 U.S.C. 102(b) be withdrawn.

CONCLUSION

Applicant respectfully maintains that all the grounds of rejections raised in the March 16, 2007 Final Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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